IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., Inc.	)	
	)	
Plaintiff/ Counterclaim Defendant,	)	
	)	C.A. No. 07-229 (GMS)
v.	)	
	)	
RANBAXY INC. and RANBAXY LABORATORIES LIMITED,	)	
	)	
Defendant/ Counterclaim Plaintiff.	)	

RANBAXY'S MOTION FOR LEAVE TO FILE A SURREPLY IN OPPOSITION TO MERCK'S MOTION FOR LEAVE TO FILE ITS FIRST SUPPLEMENTAL COMPLAINT

Defendants Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively "Ranbaxy"), respectfully request leave of the Court to file the attached Surreply Brief in Opposition to Merck's Motion for Leave to File Its First Supplemental Complaint. (Exhibit A). As explained more fully below, Merck did not include the full basis for its Motion in its Opening Brief and rather unfairly saved material for reply that should have been presented in the Opening Brief so that Ranbaxy could address it in its Answering Brief. Accordingly, Ranbaxy requests leave to file a brief surreply to address two points not raised by Merck in its Opening Brief.

On January 11, 2008, Merck filed its Opening Brief in Support of Its Motion for Leave to File its First Supplemental Complaint. (D.I. 49). In its Opening Brief, Merck briefly stated its position that it believed it could file a subsequent action against Ranbaxy to assert its patent with the Certificate of Correction under the Declaratory Judgment Act. (D.I. 49 at pp. 6, 8). In its Reply Brief, however, Merck expanded on its position presenting cases and argument that should have been presented in its Opening Brief. (D.I. 58 at pp. 6-9). Ranbaxy, therefore, requests the opportunity to briefly respond to these new arguments and newly-cited cases.

In addition, while Merck was well aware that the parties disagreed on the interpretation of "causes thereafter arising" in 35 U.S.C. § 255, Merck waited until its Reply to advance a new theory on the interpretation of this language based on language found in the reissue statute, which presents an independent statutory framework. (D.I. 58 at pp. 13-14). Given that Ranbaxy could not have anticipated that Merck would rely on the reissue statute to support its position, Ranbaxy should be given an opportunity to briefly respond to this point.

District of Delaware Local Rule 7.1.2(2) provides that "The party filing the opening brief shall not reserve material for the reply brief which should have been included in a full and fair opening brief." In interpreting a prior version of this rule, this Court has stated that the "tactic of reserving new arguments for its reply brief amounts to impermissible 'sandbagging.'" *Rockwell Technologies, LLC v. Spectra-Physics Lasers, Inc.*, 2002 WL 531555, at *3 (D.Del. Mar. 26, 2002) (*citing Jordan v. Bellinger*, 2000 U.S. Dist. LEXIS 19233, *18 (D.Del. April 28, 2000)). Given that Merck has not complied with the requirements of Local Rule 7.1.2(2), Ranbaxy respectfully requests that it be given the opportunity to briefly respond to the new arguments raised by Merck so the issues are fully presented for the Court's consideration.

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Dated: February 27, 2008

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UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 27, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF and caused the same to be served on the defendant at the addresses and in the manner indicated below:

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I hereby certify that on February 27, 2008, the foregoing document was sent to the following non-registered participants in the manner indicated:

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CERTIFICATION PURSUANT TO LOCAL RULE 7.1.1

The undersigned hereby certifies that counsel for Defendants Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively, "Ranbaxy") has conferred with counsel for Plaintiff Merck & Co., Inc. ("Merck") regarding the attached motion. Merck has indicated that it opposes the relief sought by Ranbaxy in the Motion.

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., Inc. Plaintiff/Counterclaim Defendant, v. RANBAXY INC. and RANBAXY LABORATORIES LIMITED, Defendant/Counterclaim Plaintiff.	C.A. No. 07-229 (GMS)

DEFENDANTS RANBAXY INC.'S AND RANBAXY LABORATORIES LIMITED'S SURREPLY IN OPPOSITION TO MERCK'S MOTION TO FILE ITS FIRST SUPPLEMENTAL COMPLAINT

Defendants Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively "Ranbaxy") reply to the new arguments first made in Sections II.B. and III.C. of Merck's Reply Brief in Support of its Motion for Leave to File its First Supplemental Complaint. (D.I. 58 at 6-9 and 13-14).

I. Merck's Original Declaratory Judgment Count I Bars Merck from Bringing a Later Action Against Ranbaxy Based on the Same Cause of Action.

Although Merck acknowledges that in the present action, "this Court will be prospectively resolving Merck's future causes of action underlying its declaratory judgment count" (D.I. 58 at 5) and recognizes that in its original complaint "Merck seeks a declaratory judgment that Ranbaxy will infringe in the future" under 35 U.S.C. §271(a), (b), or (c) (D.I. p. 7), Merck nonetheless maintains: "That Merck sought a declaratory judgment regarding Ranbaxy's future infringement in no way prevents Merck from bringing a later action against Ranbaxy for damages, as Ranbaxy asserts." (D.I. 58 at 7).

Merck's argument confuses the cause of action for infringement under §271, which it pled in its original complaint, with a nonexistent, separate "cause of action" for damages. Plainly, the cases cited by Merck do not stand for the principle that Merck can file a future action for damages, regardless of whether the '868 patent is held to be invalid or noninfringed in the present action. (D.I. 58 at 8). Only if Merck prevails in the present action would the Declaratory Judgment Act permit Merck to pursue future actual damages in this action, and only as further relief under 28 U.S.C. §2202. *See Polymer Indus. Prods. Co. v. Bridgestone/ Firestone, Inc.*, 347 F.3d 935, 939 (Fed. Cir. 2003).

Ranbaxy wishes to emphasize that nothing in the cases cited by Merck questions this basic principle. Although Merck asserts that Merck would be entitled to bring an action against Ranbaxy at some point in the future regardless of the outcome of the present action (D.I. 58 at 7), that argument is not supported by its citation of *Edward B. Marks Music Corp. v. Charles K. Harris Music Publ'g Co.*, 255 F.2d 518, 522 (2d Cir. 1958). Contrary to Merck's statement, *Marks* did not involve a subsequent infringement action. The case instead involved a declaratory judgment action, that was filed in 1944 and finally came to trial in 1955, resulting in a declaration of ownership of the copyrights at issue. *Id.* at 520. After the adjudication of ownership, the plaintiff moved for an adjudication of infringement and for an accounting, in the same action, as "further necessary or proper relief" under §2202. *Id.* at 522. The Second Circuit held that this further relief need not have been originally demanded, or even proved, because §2202 authorized further or new relief based on the declaratory judgment of ownership. *Id.* In its original complaint, Merck's prayer for "such other and further relief as the Court may deem just and proper under the circumstances" (D.I. 1 ¶ *h*) encompasses any future damages that may be proper under declaratory judgment Count I as "further relief" under §2202. *Marks*, 255 F.2d at 522-23. Further, Merck's Count II claim for patent infringement under §271(e)(2) by statute

permits damages to be awarded if the ANDA is approved by the FDA and commercial activity is commenced during the lawsuit. 35 U.S.C. §271(e)(4)(C). Merck's general request for "such other and further relief" also states a claim for damages for future commercial infringement under §271(e)(4)(C).

Merck further argues that in *Kaspar Wire Works, Inc. v. Leco Eng'g & Mach. Co.*, 575 F.2d 530, 536-537 (5th Cir. 1978), the Fifth Circuit concluded that the prevailing party in a declaratory judgment action "'may seek further relief in the form of damages or an injunction' in a later filed action." (D.I. 58 at 8 n.5). Merck, however, fails to acknowledge that *Kaspar* involved the preclusive effect of a declaratory judgment action that was dismissed with prejudice, but without a judicial determination of patent invalidity. *Id.* at 533-34. The Fifth Circuit held that in a subsequent infringement suit, the defendant was not precluded or collaterally estopped from raising an obviousness defense by the prior consent decree, where it was "apparent that the parties did not stipulate the validity" of the patent in their settlement agreement and this issue was not adjudicated in the consent judgment. *Id.* at 534. The court explained that under §2202, "a declaratory judgment does not embrace that aspect of *res judicata* known as merger; the prevailing party may seek further relief in the form of damages or an injunction." *Id.* at 537.[1]

Ranbaxy agrees that the Declaratory Judgment Act would provide "further relief" under Count I in the form of damages for future sales, if liability for such alleged future infringement is finally adjudicated in the present action. Merck, however, cannot evade a judgment in the present action that the '868 patent is invalid or not infringed, by filing an endless succession of

[1] Although Merck also cites *Alexander & Alexander, Inc. v. van Impe*, 787 F.2d 163 (3d Cir. 1986), that case did not involve a declaratory judgment. In dictum, the court simply stated that under §2202, "[t]he prevailing party in a declaratory judgment action subsequently may seek *further* relief." *Id.* at 166.

future, independent infringement actions based on each future sale of Ranbaxy's generic products. Nothing in the cases cited by Merck remotely suggests that a *losing* party in a declaratory judgment action can simply file another infringement action, based on the theory that each future sale of the identical product constitutes a new "cause of action" under a patent that is declared to be invalid or not infringed. As the *Restatement* confirms, "If a declaratory judgment is valid and final, it is conclusive, with respect to the matters declared, as to all persons who are bound by the judgment." Restatement (Second) of Judgments §33, comment *b*.

II. The Reissue Statute Does Not Support Merck's Argument.

For the first time in its Reply Brief, Merck argues that §252 of the reissue statute is relevant to determining the effect of a certificate of correction under §255. (D.I. 58 §III.C at 13-14). While the phrase "actions for causes thereafter arising" appears in both sections, Merck is unable to cite any case holding that the effect of a certificate of correction under §255 should be governed by the reissue statute, and *Seattle Box Co. v. Industrial Crating & Packing, Inc*., 731 F.2d 818 (Fed. Cir. 1984) is devoid of any such suggestion. Merck's argument also omits any mention of the Federal Circuit's subsequent decision in *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 756 F.2d 1574 (Fed. Cir. 1985) ("*Seattle Box II*").

The two statutory provisions are clearly independent, and provide separate rights and remedies. Under the reissue statute, if a defect in a patent can be corrected without changing the language of the claims, the correction relates back to the original issue date of the patent, and damages may be awarded for infringement occurring prior to the reissue date. 35 U.S.C. §252, first paragraph. Such relief is clearly precluded under §255, which makes the certificate ineffective for any purpose when a certificate issues after the cause of action arose, regardless of whether original claims are present in the corrected patent, under *Southwest Software Inc. v. Harlequin Inc*., 226 F.3d 1280 (Fed. Cir. 2000).

The reissue statute provides for absolute intervening rights, granting a person who made, purchased or offered to sell anything prior to grant of a reissue patent, the unrestricted right to continue infringing sales of such articles after the reissue patent is granted, if such activity does not infringe any valid claim that was present in the original patent. 35 U.S.C. §252, second paragraph, first sentence; *see Seattle Box II*, 756 F.2d at 1578-79. Because the effect of a certificate of correction is not subject to this exception for original claims, the rights of an accused infringer are broader with respect to a patent that is corrected under §255. Moreover, the court may provide for continued manufacture, use, offer for sale, or sale of an otherwise infringing article after the reissue patent is granted, "to the extent that the court deems equitable for the protection of investments made or business commenced before the grant of the reissue." 35 U.S.C. §252, second paragraph, second sentence; *see Seattle Box II*, 756 F.2d at 1579-80 ("one may be able to continue to infringe a reissue patent if the court decides that equity dictates such a result").

Because §255 does not expressly incorporate each of the specific rights and remedies set forth in the reissue statute, including the express provisions distinguishing relief for infringement of original and newly added claims, and the further limitations providing both absolute and equitable intervening rights, Ranbaxy submits that the effect of a certificate of correction under §255 cannot simply be based on the independent remedial provisions of the reissue statute. Furthermore, because a certificate of correction cannot relate back to the original patent issue date, the policy expressed in the reissue statute suggests that intervening rights should similarly limit liability for infringement based on sales which occur after issuance of a certificate of correction under §255, even in the absence of *Southwest Software Inc. v. Harlequin Inc.*, 226 F.3d 1280 (Fed. Cir. 2000). Such equitable intervening rights, permitting continued commercial sale of drug products made or imported after the grant of a reissue patent, could certainly be

based on a generic drug manufacturer's investment in new manufacturing facilities and the expenses of preparing and pursuing an ANDA, acting in good-faith reliance on a facially invalid original patent. *See Seattle Box II*, 756 F.2d at 1580 ("the remedy of intervening rights is calculated to protect an infringer's preexisting investments and business. Prior business commitments, such as previously placed orders and contracts, are one such example.").

III. Conclusion.

Because Merck specifically pled future infringement as its sole cause of action under §271(a), (b), or (c) in Count I of its original declaratory judgment complaint, and Ranbaxy independently pled invalidity and noninfringement in its declaratory judgment counterclaims, the issues of patent validity and future infringement will be finally adjudicated in the present declaratory judgment actions, and Merck will be forever barred from filing a future infringement action by an adverse judgment in this case.

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Dated: February 27, 2008